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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,472	09/20/2000	Menzo Havenga	4489US	8505

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EXAMINER

MARVICH, MARIA

ART UNIT PAPER NUMBER

1636

DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/665,472

Applicant(s)

HAVENGA ET AL.

Examiner

Maria B Marvich, PhD

Art Unit

1636

--Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 22 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1,4,7,8,13,14,16,18,19 and 21-24.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____


TERRY MCKELVEY
PRIMARY EXAMINER

Continuation of 2. NOTE: The proposed amendment would raise the following new issues that would require new consideration: Claim 1 recites that the recombinant chimeric adenoviral vector is based on a first adenovirus of subgroup C and that the tissue tropism for dendritic cells is provided by a non-native fiber protein substituted for a fiber protein of the first adenovirus. These amendments have changed the scope of the claims by specifically limiting the vector as based on adenovirus of subgroup C whose native fiber protein is substituted with a non-native fiber from adenovirus 11, 16, 35, 51 and 40L.

Continuation of 5. does NOT place the application in condition for allowance because: the applicant's arguments are moot in view of the non-entry of the after final amendment.

On pages 7-8 of the amendment filed 12/17/02, applicant traverses the rejection of claims 1, 4, 7-8, 13-14, 16, 18, 19 and 21-22 under 35 U.S.C 102(e) as anticipated by Crystal et al. Applicant argues that Crystal et al neither expressly nor inherently teach the instant invention. Specifically, Crystal et al do not provide for modifications in adenoviral fiber proteins directed to provide tropism to target cells and specifically to dendritic cells. Instead, the reference to the teachings of Crystal et al is disputed as broadly describing all chimeric adenoviral vectors with switched fiber proteins. Teachings of modifications directed to altered tropism specifically for dendritic cells are said to be attributed to Crystal et al based upon the theory of inherency. While according to the MPEP 2112, the examiner must provide a basis in fact or technical reasoning to demonstrate that the inherent characteristics necessarily flows from the teachings of the prior art, support for inherency is drawn from the specification of the instant invention. Applicants argue that the instant invention is distinguishable over the prior art by teaching that selected adenoviral serotypes or groups of serotypes with particularly advantageous tropism for dendritic cells. Specifically, they teach that not all adenovirus have tropism for dendritic cells and rather the art of selecting adenoviral fibers for tropism to dendritic cells as well as the tropism of each serotype is unpredictable. Further these teachings of the specification provide evidence that chimeric fibers made according to the teachings of Crystal et al would not possess the ability to bind and infect dendritic cells.

Applicants arguments filed 8/22/03 have been considered but are not persuasive. The elements disputed as missing from the teachings of Crystal et al, modifications directed to providing tropism to desired target cells especially dendritic cells, attribute to the claim processes that are not recited in the claim. Instead, applicants recite a chimeric adenoviral vector comprised of a first adenovirus capsid from Ad11, Ad 16, Ad35, Ad51, Ad40L and a second capsid from subgroup C adenovirus. The first capsid directs tropism for dendritic cells. This product is identical to that of Crystal et al. Therefore, the claimed properties are presumed to be inherent (see MPEP 2112.01). "Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established". Applicants have not provided evidence showing the prior art products do not necessarily possess the characteristics of the claimed product. As the prior art adenoviral vector and the adenoviral vector of the instant invention are identical and these facts are not in dispute, it would necessarily flow that the properties associated with these vectors are the same.